K112022

SEP 22 2011

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Submitter

Advanced Instrumentations, Inc.
6800 N.W. 77th Court
Miami, Fl 33166
Telephone: 305-477-6331
Fax: 305-477-5351

Registration # 1066270

Official correspondent :

Jorge Millan, PhD
Email: jmillan@hiatec.org
601 West 20 St
Hialeah, FL 33010
Phone : (305) 925-1260

Date Prepared:

July 13, 2011

Device name and classification:

- **Device Name:** DUS-3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System
- **Classification Name:** 892.1560 System, Imaging, Pulsed echo, Ultrasonic
  Product code: IYO
  892.1570 Transducer, Ultrasonic, Diagnostic
  Product code: ITX
- **Regulatory Class:** II

Predicate Device:

DUS3/DUS6 Digital Ultrasonic Diagnostic Imaging System. K091680 Manufacturer: EDAN Instruments

Device Description:

The DUS-3000/DUS-3000Plus Digital Ultrasound Diagnostic Imaging System is a portable digital ultrasonic diagnostic B/W system applied in ultrasound diagnostic examination of abdominal, obstetrical, small parts, gynecological, orthopedic, cardiac, and urological applications.

It is designed to produce ultrasound waves into the body tissue and to present the returned echo information on the monitor. The resulting information is displayed in five display modes: B-Mode, 2B-Mode, 4B-Mode, M-Mode or the combined mode (i.e. B/M-Mode). This system controlled by software is a Track 1 device that employs an array of probes that include linear array, convex linear array, micro convex linear array, transrectal and transvaginal with a frequency range of approximately 2.5MHz-10MHz. The system consists of a main unit, a display and transducers.

Intended Use:

The DUS-3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System is intended for diagnostic ultrasound imaging analysis in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The DUS-3000/DUS-3000Plus is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus; Abdomen; Pediatrics; Small Organ; Neonatal Cephalic; Cardiology; Peripheral Vessel; Musculo-skeleton (both Conventional and Superficial); Urology (including prostate); Transrectal and Transvaginal.

Effectiveness and Safety Contraindications:

Clinical Test

Clinical testing is not required

Non-clinical test:

The following safety standards are conducted on the subject device:

1. IEC 60601-1 Electrical Safety
2. IEC 60601-1-2 Electromagnetic Compatibility

3. Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9 2008
4. ISO 10993-1, ISO 10993-5 and ISO 10993-10

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use, same material components, same manufacturing process, same design principle, same electrical classification, same measurement mode and same accuracy as the predicate device.

Substantially Equivalent Determination:

Verification and validation testing was done on the DUS 3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System. This premarket notification submission demonstrates that DUS-3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Advanced Instrumentations, Inc.
% Jorge Millan, Ph.D.
Executive Director
Hialeah Technology Center, Inc.
601 West 20 St
HIALEAH FL 33010

SEP 22 2011

Re: K112022
Trade/Device Name: DUS-3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: September 13, 2011
Received: September 15, 2011

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DUS-3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

DUS 3000	DUS 3000 Plus
E613	E611-1
L743	E741
C321	L741
C363-1/C343-1	C321-1
	C361-1/C341

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name:

DUS-3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System

Indications for Use:

The DUS-3000/DUS-3000Plus Digital Ultrasonic Diagnostic Imaging System is intended for diagnostic ultrasound imaging analysis in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The DUS-3000/DUS-3000Plus is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus; Abdomen; Pediatrics; Small Organ; Neonatal Cephalic; Cardiology; Peripheral Vessel; Musculo-skeleton (both Conventional and Superficial); Urology (including prostate); Transrectal and Transvaginal.

Prescription Use _X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 Digital Ultrasonic Diagnostic Imaging System

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-Skeletal (Conventional)	N	N				N	
Musculo-Skeletal (Superficiall)	N	N				N	
Intravascular							
Other (specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular	N	N				N	
Other (specify)							

N = new indication xx- previously cleared by FDA: E – added under this appendix

Additional comments: Combined mode B + M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 5/11/2022

Digital Ultrasonic Diagnostic Imaging System
510k Submission

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 Plus with E613 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficiall)							
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (specify)							

N = new indication xx- previously cleared by FDA: E – added under this appendix

Additional comments: Combined mode B + M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 Plus with L743 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficiall)							
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (specify)							

N = new indication xx- previously cleared by FDA: E – added under this appendix

Additional comments: Combined mode B + M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 6/17/2022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 Plus with L743 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)	N	N				N	
Musculo-Skeletal (Superficial)	N	N				N	
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	
Other (specify)							

N = new indication xx- previously cleared by FDA: E – added under this appendix

Additional comments: Combined mode B + M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 Plus with C321 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal	N	N				N	
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficiall)							
Intravascular							
Other (specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular							
Other (specify)							

N = new indication xx- previously cleared by FDA: E – added under this appendix

Additional comments: Combined mode B + M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 Plus with C363-1 /C343-1 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficial)							
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (specify)							

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Additional comments: Combined mode B + M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Robb

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 11/2022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 Plus Digital Ultrasonic Diagnostic Imaging System

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-Skeletal (Conventional)	N	N				N	
Musculo-Skeletal (Superficial)	N	N				N	
Intravascular							
Other (specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular	N	N				N	
Other (specify)							

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Additional comments: Combined mode B + M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 with E611-1 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficiall)							
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (specify)							

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 with L741 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)	N	N				N	
Musculo-Skeletal (Superficial)	N	N				N	
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	
Other (specify)							

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Additional comments: Combined mode B - M

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Digital Ultrasonic Diagnostic Imaging System
510k Submission

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 with E741 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficiall)							
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (specify)							

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 with C321-1 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal	N	N				N	
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficiall)							
Intravascular							
Other (specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular							
Other (specify)							

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022

Diagnostic Ultrasonic Indications for Use Form

DUS 3000 with C361-1/C341 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative(Specify)							
Intra-operative(Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-Skeletal (Conventional)							
Musculo-Skeletal (Superficiall)							
Intravascular							
Other (specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (specify)							

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Mary S Patel

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112022